

acid formulation to be discontinued, said intermediate release nicotinic acid formulation exhibiting *in vivo* stair-stepped absorption profile when a convoluted plasma curve for nicotinic acid released from the intermediate release nicotinic acid formulation is deconvoluted using the Wagner-Nelson method, wherein the stair-stepped absorption profile is generally characterized by three phases in which

up to about 19% of the nicotinic acid dose administered is absorbed between about 1 and about 4 hours following ingestion at the end of the first phase;

between about 78% and about 100% of the nicotinic acid dose administered is absorbed between about 4 and about 8 hours following ingestion at the end of the second phase; and

between about 86% and about 100% of the nicotinic acid dose is absorbed between about 5 and about 9 hours following ingestion at the end of the third phase.

9-23-00
B¹ could
(3)(Amended) ^{ONCE} An intermediate release nicotinic acid formulation suitable for oral administration ~~one~~ a-day as a single dose for treating hyperlipidemia without causing treatment-limiting hepatotoxicity and treatment-limiting elevations in uric acid or glucose levels or both [for hepatotoxicity] to a level which would require use of said intermediate release nicotinic acid formulation to be discontinued, said intermediate release nicotinic acid formulation exhibiting an *in vivo* stair-stepped absorption profile when a convoluted plasma curve for nicotinic acid released from the intermediate release nicotinic acid formulation is deconvoluted using the Wagner-Nelson method, wherein the stair-stepped absorption profile is generally characterized by three phases in which

nicotinic acid is absorbed at a rate of up to about 9% of the nicotinic acid dose administered per hour between about 1 and about 4 hours following ingestion at the end of the first phase; and

nicotinic acid is absorbed at a rate of between about 14% and about 26% of the nicotinic acid dose administered per hour between about 5 and about 8 hours following ingestion at the end of the second phase.